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Dated: March 9, 2004 Signature: _____

(Arnold H. Krumholz)

EXPEDITED PROCEDURE

Group Art Unit: 3738

Docket No.: HAMMON 3.3-002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: _____ :
Wasserman et al. _____ :
_____ :
Application No.: 09/936,721 _____ : Group Art Unit: 3738
_____ :
_____ :
Filed: December 19, 2001 _____ : Examiner: K. R. Landrem
_____ :
For: ARTIFICIAL URINARY DIVERSION _____ :
SYSTEM _____ :

RESPONSE UNDER 37 CFR 1.116

MS AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Office Action dated October 3, 2003, in which claims 29-65 were finally rejected, and claims 66-68 were allowed, the following remarks are respectfully submitted.

REMARKS/ARGUMENTS

Applicants initially note with appreciation the Examiner's indication that claims 66-68 are allowable. However, in view of the following comments and analysis, it is respectfully submitted that, in fact, all of the claims in this application are in condition for allowance, and reconsideration and allowance of these claims are therefore respectfully solicited.

Claims 29-31, 50, 54 and 56 have been rejected as being anticipated by Dobos-Hardy under 35 U.S.C. § 102(b). The

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Examiner contends that Dobos-Hardy discloses a device having first, second and third cross-sectional areas relating, respectively, to numerals 7, 12 and 6 therein, at least one cross-sectional area of the first and second areas being smaller than that of the third area. The first cross-sectional area is said to have a portion larger in cross-sectional area than the second area, and an inlet 5 is located in the first area, and outlet 3 with sphincter mechanism 17 is disposed in the third area, with pressure allegedly acting as a control means for the valve thus regulating pressure. The internal structures are said to be modular, and the outer cover 1 is said to provide a continuous outer surface. Tube 8 is said to act as a fluid guide means for guiding fluid from the third area to the first area, and outlet 4 is said to be useful as expulsion means for removing liquid from the device. This rejection is respectfully traversed for the reasons set forth hereinafter.

Turning to the Dobos-Hardy reference itself, this patent is directed to an implantable artificial kidney device. Thus, the device shown in FIG. 1 of this patent includes a blood inlet 3 for connection to the renal artery and a blood outlet 4 for connection to the renal vein, with a urine outlet 5 for connection to the ureter of the living human body. Within the device, the blood is channeled to blood tube 8 surrounded by blood tube 9 for removal of the urine therefrom. The second portion of the system in tubule 7 is similar to the portion in glomerules 6 so that at crossover point 12 blood tube 8 connects to blood tube 13 which is the outer tube in this portion of the device. Reference is also made to FIG. 3 showing a control valve 17 formed as a non-return valve for not allowing the increase of blood pressure above 75 mm of mercury.

The present application, on the other hand, is directed to an artificial bladder device. In this device, the urinary bladder comprises the required first, second and third

portions, including the first and second cross-sectional surfaces being smaller than the third cross-sectional surface. Claim 29 specifically requires that the device also include a sphincter mechanism, which by definition can control the flow therethrough in either direction, as well as control means for controlling the sphincter mechanism. Of course, since the cited Dobos-Hardy reference does not even relate to a urinary bladder, it certainly does not include a sphincter mechanism, or for that matter any means for controlling the sphincter mechanism, as is the case with a bladder in general. The Examiner's reference to control valve 17 is inapposite, particularly since this is merely a non-return valve which prevents an increase in blood pressure above 75 mm of mercury. It certainly does not act as a sphincter mechanism, which again can control the flow in either direction, nor is there any control means whatsoever provided for controlling the sphincter mechanism, as is the case with a urinary bladder, as opposed to an artificial kidney, such as that of Dobos-Hardy.

It is therefore abundantly clear that the Dobos-Hardy reference not only fails to anticipate these claims, but does not obviate these claims in any way, shape, or form. These claims are directed to a different device (namely, an artificial urinary diversion apparatus), which includes elements clearly not suggested even in the artificial kidney device of Dobos-Hardy, including a sphincter mechanism for opening and closing the outlet and control means for controlling the sphincter mechanism itself. It is therefore respectfully submitted that these claims are clearly patentable, and reconsideration of the rejection of these claims is respectfully solicited.

Claims 32-49 have been rejected as being unpatentable over Dobos-Hardy in view of Yamazaki under 35 U.S.C. § 103(a). After admitting that Dobos-Hardy fails to include a pump and a

power supply, the Examiner contends that Yamazaki teaches a device comprising a screw pump 21 to move fluid through the device by means of a driving motor 5 comprised of a power battery 17 connected to an external charger, sensors 26-28 for detecting conditions within the device, and an alarm signal to draw attention to changing conditions. The Examiner contends that the screw pump is used because it can be made simple in construction and small in size while providing high durability and reliability. It is thus concluded that it would be obvious to modify Dobos-Hardy by incorporating the pump, power supply and signals taught by Yamazaki to provide a small device that is durable and reliable. This rejection is respectfully traversed in view of the above arguments and for the reasons set forth hereinafter.

Applicants, of course, reiterate all of their above-noted contentions with respect to the clear deficiencies of Dobos-Hardy with respect to the overall subject matter and to the specific nature of the present invention. As for claims 32-49 themselves, the Examiner initially admits that Dobos-Hardy fails to include a pump and power supply, for example. Yamazaki itself relates to an auxiliary artificial heart. For this reason alone, there is clearly no basis for even combining the subject matter of Dobos-Hardy with Yamazaki in the first instance. In any event, however, even if there were some reason to include the pump, power supply, and signals of Yamazaki in the device of Dobos-Hardy, in view of the deficiencies of the primary reference as discussed above, there would still not be a suggestion of the presently claimed artificial urinary diversion apparatus. It is therefore clear that these claims are also patentable over the cited references, and reconsideration and allowance of these claims is also respectfully solicited.

Claims 51-53 and 55 have been rejected as being unpatentable over Dobos-Hardy in view of Yamazaki under

35 U.S.C. § 103(a). The Examiner admits that Dobos-Hardy fails to disclose a plurality of inlets and valves, but concludes that it would be obvious to incorporate a plurality of key components such as inlets and valves, since it is a mere duplication of the essential working parts of the device involving only routine skill. This rejection is respectfully traversed in view of the above arguments and for the reasons set forth hereinafter.

Applicants again reiterate all of their above-noted contentions with respect to the deficiencies of both of these references. Once again, as above, even though these references are not properly combinable without a suggestion to do so, even if they were so combined, and even if the valves and inlets of Yamazaki were somehow incorporated into Dobos-Hardy, the presently claimed artificial urinary diversion device would clearly not be disclosed or suggested thereby. Again, reconsideration of these rejections is respectfully solicited.

Finally, claims 57-65 have been rejected as being unpatentable over Dobos-Hardy in view of Boveja *et al.* under 35 U.S.C. § 103(a). After admitting that Dobos-Hardy fails to disclose a fixing element for attaching the apparatus to the human body, the Examiner refers to FIG. 4 of Boveja *et al.* as teaching an external stimulator 42 for treating urological disorders comprising an expandable fixing element 44 to position the apparatus, and connection means 38 for connecting the fixing element to the apparatus. The Examiner thus concludes that it would be obvious to modify the apparatus of Dobos-Hardy incorporating the external fixation means taught by Boveja *et al.* to secure the apparatus to the patient. This rejection is respectfully traversed in view of the above arguments and for the reasons set forth hereinafter.

Applicants again reiterate their above-noted contentions with respect to the clear deficiencies of Dobos-Hardy with respect to each of these claims. As for Boveja

et al., this patent is directed to external stimulators for, *inter alia*, urological disorders. However, the Examiner does not even attempt to allege that there would be some basis for one of ordinary skill in this art to combine this reference with Dobos-Hardy. Indeed, it is clear on its face that this combination of references, in the first instance, has been made only as a result of pure hindsight based upon applicants' own disclosure. There is nothing in the Boveja *et al.* reference which suggests that it would be useful, for example, in connection with an artificial kidney device. In any event, the external stimulator 42 in Boveja *et al.*, as shown in FIG. 4 thereof, is clipped to a belt 44. It then inductively coupled to the lead-receiver 34 in the manner shown in FIG. 5 thereof. It is not seen how this relates specifically to the combination of the artificial urinary diversion apparatus of claim 57 including a fixing element for fixing the apparatus in a human body. This clearly does not relate to the belt 44 shown in Boveja *et al.* Furthermore, there is no suggestion whatsoever for the limitations of claims 59-65 therein, irrespective of whether or not Boveja *et al.* were properly combinable with the primary reference. It is therefore respectfully submitted that these claims are clearly patentably distinguishable over the references, and reconsideration and allowance of these claims is therefore respectfully solicited.

Applicants respectfully submit that all of the claims in this application are now in condition for allowance, and such action is therefore respectfully solicited. If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

Dated: March 9, 2004

Respectfully submitted,

By 

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